

CLAIMS

What we claim is:

1. A method of determining a new anticoagulant therapy factor (nATF) comprising the steps of developing a series of analog electrical voltage signals having voltage amplitudes proportional to an optical density of a liquid sample containing fibrinogen;
 - 5 a. converting the developed analog voltage signals into a series of digital voltage value signals;
 - b. adding a coagulant into the liquid sample, thereby producing an abrupt change in the optical density of the liquid sample, said abrupt change producing an abrupt change in the amplitude of the electrical analog signals which, in turn, produces an abrupt change in the value of said digital voltage signals, the value of said digital voltage signals being directly indicative of fibrinogen concentration in the liquid sample;
 - 10 c. recording an instant time t_0 of said abrupt change in said value of said digital voltage signal;
 - d. monitoring said voltage digital signal values for a first predetermined fibrinogen concentration quantity c_1 ;
 - e. recording an instant time t_1 and the value of the voltage digital signal of said first predetermined fibrinogen concentration quantity c_1 ;
 - 15 f. monitoring said voltage digital signal values for further fibrinogen concentration quantities;
 - g. recording an instant time t_{MAP} and the value of the voltage digital signal of said predetermined fibrinogen concentration quantity c_{MAP} ;
 - 20 h. recording an elapsed time between t_0 and t_{MAP} which defines a time to maximum acceleration from coagulant injection in step (c);
 - i. monitoring for a differential change in the voltage digital signal values that include a predetermined fibrinogen concentration quantity c_{MAP} ;
 - j. said fibrinogen concentration quantity c_{MAP} and said time
- 25 t_{MAP} defining a maximum acceleration point (MAP) and a time to maximum acceleration from coagulant injection (TX) being measured as the elapsed time from the time of the coagulant injection t_0 to the time to maximum acceleration t_{MAP}, and each of the quantity c_{MAP} and said time t_{MAP} having a predetermined
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range starting prior to, at a time $t_{<MAP}$, and ending after said maximum acceleration point (MAP), at a time $t_{>MAP}$;

5 k. monitoring voltage digital signal values at times $t_{<MAP}$ and $t_{>MAP}$ for respective predetermined fibrinogen concentration quantities $c_{<MAP}$ and $c_{>MAP}$, with the difference between quantities $c_{<MAP}$ and $c_{>MAP}$ being a first differential IUX;

10 l. monitoring voltage digital signal values at time t_{EOT} and recording an instant time t_{EOT} the value of the voltage digital signal of said predetermined fibrinogen concentration quantity c_{EOT} , with the difference between quantities c_1 and c_{EOT} being a second differential IUT, the first differential being divided by the second differential to define a percentage of the total voltage digital signal value change covered by an overall range defining a new fibrinogen transformation rate (nFTR), where $nFTR = IUX/IUT$;

15 wherein a maximum acceleration ratio (XR) is determined by the time to maximum acceleration from the coagulant injection (TX) divided by a mean normal TX value (MNTX) of a sample of presumed normal patients;

wherein the new anticoagulant therapy factor (nATF) is expressed by the following relationship:

$$nATF = XR^{(2-nFTR)}$$

20 2. The method of claim 1, wherein TX represents a time interval of the mean of a sample of presumed normal patients.

3. The method of claim 1, wherein the sample of mean normal patients is about 20 patients.

4. The method of claim 1, wherein the MNTX is the mean of the TX of the plurality of samples from at least twenty (20) normal people.

25 5. The method of claim 1, wherein the sample of mean normal patients is about equal to or greater than 20 patients.

6. The method of claim 1, wherein the predetermined range starting prior to and ending after said maximum acceleration point (MAP) is from about a time $t_{<MAP}$ occurring 0.4 seconds prior to time t_{MAP} to a time $t_{>MAP}$ occurring 0.4 seconds after the time t_{MAP} .

30 7. The method according to claim 1, wherein said liquid sample is blood plasma.

8. The method according to claim 1, wherein the coagulant which is injected into the sample is thromboplastin with calcium ion.
9. The method according to claim 1, wherein the analog electrical voltage signal is developed by transmitting a light beam through a plasma sample and sensing the variations in light passing therethrough to develop corresponding variations in the electrical signal produced.
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10. An apparatus for determining a new anticoagulant therapy factor (nATF) comprising:
 - a. means including a light source, a test tube, a photocell, a battery, and a variable resistor all for developing an analog electric voltage signal having an amplitude proportional to an optical density of a liquid sample containing fibrinogen;
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 - b. means including an A/D converter and a computer both cooperating for converting and recording the developed analog signal into a series of digital voltage signal values;
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 - c. means for injecting a coagulant into a liquid sample, thereby producing an abrupt change in the optical density of the liquid sample, said abrupt change producing a change in the amplitude of the electrical analog signals, which, in turn, produces an abrupt change in the value of said digital voltage signals, the value of said digital voltage signals being directly indicative of fibrinogen concentration in the liquid sample;
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 - d. means for recording an instant time t_0 of said abrupt change in said value of said digital voltage signal;
 - e. means, including a computer, for monitoring said voltage digital signal values for a first predetermined fibrinogen concentration quantity c_1 ;
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 - f. means for recording an instant time t_1 and the value of the voltage digital signal of said first predetermined fibrinogen concentration quantity c_1 ;
 - g. means, including a computer, for monitoring said voltage digital signal values for further fibrinogen concentration quantities;
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 - h. means for recording an instant time t_{MAP} and the value of the voltage digital signal of said predetermined fibrinogen concentration quantity c_{MAP} ;

- i. means for recording an elapsed time between t_0 and t_{MAP} which defines a time to maximum acceleration from coagulant injection in step (c);
- j. means, including said computer, for monitoring for a differential change in the voltage digital signal values that include a predetermined fibrinogen concentration quantity c_{MAP} ;
- 5 k. said fibrinogen concentration quantity c_{MAP} and said time t_{MAP} defining a maximum acceleration point (MAP) and a time to maximum acceleration from coagulant injection (TX) being measured as the elapsed time from the time of the coagulant injection t_0 to the time to maximum acceleration t_{MAP} , and each of the quantity c_{MAP} and said time t_{MAP} having a predetermined range starting prior to, at a time $t_{<MAP}$, and ending after said maximum acceleration point (MAP), at a time $t_{>MAP}$;
- 10 l. means, including said computer, for monitoring voltage digital signal values at times $t_{<MAP}$ and $t_{>MAP}$ for respective predetermined fibrinogen concentration quantities $c_{<MAP}$ and $c_{>MAP}$, and for calculating the difference between quantities $c_{<MAP}$ and $c_{>MAP}$ to provide a first differential (IUX);
- m. means, including said computer, for monitoring voltage digital signal values at time t_{EOT} and recording an instant time t_{EOT} the value of the voltage digital signal of said predetermined fibrinogen concentration quantity c_{EOT} , and for calculating the difference between quantities c_1 and c_{EOT} to provide a second differential (IUT);
- 15 n. means, including said computer, for dividing the first differential (IUX) by the second differential (IUT) to define a percentage of the total voltage digital signal value change covered by an overall range defining a new fibrinogen transformation rate (nFTR), where $nFTR = IUX/IUT$;
- 20 o. means, including said computer, for dividing the time to maximum acceleration from the coagulant injection (TX) by a mean normal TX value of a sample of presumed normal patients to provide a maximum acceleration ratio (XR) which is factored to the (2-nFTR) power with the product thereof being the new anticoagulant therapy factor (nATF) is expressed by the following relationship: $nATF = XR^{(2-nFTR)}$.

11. The apparatus according to claim 10, wherein said liquid sample is blood plasma.
12. The apparatus according to claim 10, wherein said coagulant which is injected into the sample is thromboplastin with calcium ion.
- 5 13. The apparatus according to claim 10, wherein the analog electrical voltage signal is developed by transmitting a light beam through a plasma sample and sensing the variations in light passing therethrough to develop corresponding variations in the electrical signal produced.